UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

FAYE CAFFERTY and DOANE CAFFERTY,

Plaintiffs,

-v.-

5:08-cv-0179 (NPM/ATB)

CAYUGA MEDICAL CENTER; ARLEO EYE INSTITUTE; ROBERT ARLEO M.D.; and ALCON LABORATORIES, INC.,

Defendants.

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Neal P. McCurn, Senior District Judge

Memorandum, Decision and Order

I. Introduction

This personal injury action was removed to this court, which has jurisdiction pursuant to 28 U.S.C. § 1332. By their complaint, plaintiffs, Faye Cafferty ("Mrs. Cafferty") and her husband, Doane Cafferty (collectively, "Plaintiffs"), set forth seven causes of action stemming from injuries which allegedly occurred due to the negligence of defendants Cayuga Medical Center ("CMC"); Arleo Eye Institute and Robert Arleo, M.D. (collectively, "Dr. Arleo"); and Alcon Laboratories, Inc. ("Alcon") (collectively, "Defendants"). In her complaint, Mrs. Cafferty asserts claims of negligence against all defendants, including a separate cause of action based on the doctrine of res ipsa loquitur. In addition, Mrs. Cafferty alleges a claim for breach of implied warranty of merchantability against Alcon[1] and a claim for medical malpractice based on lack

[1] Plaintiffs have withdrawn their claim against Alcon, set forth in Count III of the complaint, for breach of implied warranty of merchantability. Accordingly, that claim is

of informed consent against Dr. Arleo. All claims are pursuant to New York common law.

Prior to the close of discovery, Alcon filed a motion to dismiss the complaint as against it for failure to state claims upon which relief may be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure based on federal preemption of certain of the claims, as well as a motion to stay discovery pending resolution of that motion. See Dkt. No. 20. Discovery is now complete. Consequently, Alcon's motion to stay discovery is denied as moot. Alcon thereafter filed a motion for summary judgment against Plaintiffs seeking dismissal of all claims against it, based on, among other things, the same federal preemption argument it set forth in its earlier motion to dismiss. See Dkt. No. 57. Accordingly, the motion to dismiss need not be separately decided, as the issues it presents will be addressed with the motion for summary judgment.

Also pending is a motion for summary judgment by Plaintiffs against all defendants as to the issue of res ipsa loquitur, see Dkt. No. 52 as well as a cross motion for summary judgment by Alcon against Plaintiffs on that same issue, see Dkt. No. 69. Defendants CMC and Dr. Arleo have also filed separate motions for summary judgment against Plaintiffs. See Dkt. Nos. 56 and 53, respectively. Papers in opposition to each motion as well as reply papers have been filed. Decision regarding the pending motions is rendered on the papers submitted without oral argument.

II. Legal Standard

A motion for summary judgment shall be granted "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no

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dismissed.

genuine issue as to any material fact and that the movant is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). See also United Transp. Union v. Nat'l R.R. Passenger Corp., 588 F.3d 805, 809 (2d Cir. 2009). "In ruling on a motion for summary judgment, the district court may rely on any material that would be admissible or usable at trial." Major League Baseball Props., Inc. v. Salvino, Inc., 542 F.3d 290, 309 (2d Cir. 2008) (internal quotation and citation omitted).

The movant has the burden to show that no genuine factual dispute exists. See Vermont Teddy Bear Co., Inc. v. 1-800 Beargram Co., 373 F.3d 241, 244 (2d Cir. 2004) (citing Adickes v. S. H. Kress & Co., 398 U.S. 144, 157, 90 S.Ct. 1598 (1970)). Moreover, when the court is deciding a motion for summary judgment, it must resolve all ambiguities and draw all reasonable inferences in the non-movant's favor. See id.

When deciding whether a material issue of fact is in dispute, the court is cognizant that "[a] fact is material when it might affect the outcome of the suit under governing law." Tracy v. Freshwater, 623 F.3d 90, 95 (2d Cir. 2010) (internal citation omitted). Also, a material fact is genuinely in dispute "if 'the evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" Bessemer Trust Co., N.A. v. Branin, 618 F.3d 76, 85 (2d Cir. 2010) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 2510 (1986)).

It should also be noted that, pursuant to Local Rule 7.1(a)(3), the court deems admitted any statement of material fact that is not specifically controverted by the opposing party. See N.D.N.Y. R. 7.1(a)(3).

III. Factual Background

On October 12, 2005, Mrs. Cafferty underwent eye surgery performed by

Dr. Arleo at a CMC facility, during which products manufactured by Alcon were used. Thereafter, Mrs. Cafferty presented with certain symptoms and was later diagnosed with Toxic Anterior Segment Syndrome ("TASS") in her left eye.

TASS is an inflammation that occurs when unwanted material gains access to the anterior chamber of the eye, causing a toxic reaction. In this case, Mrs. Cafferty underwent clear lens extraction of the left eye with implantation of an intraocular lens. She thereafter presented with symptoms that each expert in this case agrees are consistent with TASS.[2]

While all of the experts agree that there are many possible causes of TASS, they also agree that in the majority of TASS cases, its exact cause is often difficult to identify and in Mrs. Cafferty's case, the specific cause of her TASS is unknown. Drs. Armesto and Mamalis agree that TASS is related to an unwanted material gaining access to the anterior segment of the eye. Dr. Armesto states in his report that TASS occurs when a toxic substance enters the eye at the time of surgery. Dr. Mamalis states in his report that the material gains access either during surgery or immediately after, but at his deposition, Dr. Mamalis agreed that TASS occurs during a surgical procedure, and that Mrs. Cafferty's TASS arose from her surgery. Later, by affidavit, Dr. Mamalis clarified that "while TASS frequently results from a toxic substance introduced during surgery, it can also develop due to a toxic material introduced in either pre-operative or post operative settings. TASS does not necessarily always occur because of a toxic substance

[2] The record here includes, among other things, the reports of four experts: David M. Armesto, M.D., proffered by Plaintiffs; Nick Mamalis, M.D., proffered by defendants Arleo and CMC; and Bernard A. Milstein, M.D. and Rick W. Fraunfelder, M.D., each proffered by defendant Alcon. See Exs. D, F, J and K to Decl. of Oliver N. Blaise III, Apr. 27, 2010, Dkt. No. 52.

introduced into the anterior segment of the eye during surgery while the opthalmic surgeon is present." Aff. of Nick Mamalis, M.D., April 22, 2010, ¶ 7, Dkt. No. 66-1.

While Dr. Mamalis testified that his review of the medical records in this case do not reveal a specific cause of Mrs. Cafferty's TASS, he also explained that it is not uncommon to be unable to identify the exact cause of TASS. According to Dr. Mamalis, most TASS cases arise from one of two main sources: (1) cleaning and sterilization of opthalmic instruments and (2) fluids, solutions, medications and products used during the surgery. Because TASS does not present itself until 24-48 hours after surgery, it is difficult to identify a specific cause because by that time, the instruments used during surgery have been cleaned and sterilized and the medications or solutions used during surgery are disposed of, preventing the discovery of direct evidence of contamination.

Here, none of the experts were able to identify a specific cause of Mrs. Cafferty's TASS based on the medical records and the video recording of the surgery. In fact, several of the experts commented that the surgery was performed in an "expert" (Dr. Armesto) and "very competent and efficient" (Dr. Milstein) manner, "without any complications or breaches in technique" (Dr. Mamalis). Dr. Armesto opined that it is likely that one of the two main sources of TASS outlined by Dr. Mamalis caused Mrs. Cafferty's TASS. However, he noted that the records he reviewed did not contain a complete comprehensive analysis of every solution, substance, product or cleaning process in her case.

IV. Discussion

A. Pre-emption

Alcon argues that Plaintiffs' causes of action for negligence and breach of

warranty regarding its ReSTOR® lens and DisCoVisc® are pre-empted by the Medical Devices Amendments to the Federal Food, Drug and Cosmetic Act and must be dismissed. Because Plaintiffs have withdrawn the breach of warranty claim, the court need not address the pre-emption issue in that regard.

The Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., requires approval by the Food and Drug Administration ("FDA") for the introduction of new drugs into the market. See Riegel v. Medtronic, Inc., 552 U.S. 312, 315, 128 S.Ct. 999, 1002 (2008). The Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 301c et seq., "imposed a regime of detailed oversight," changing the then existing regulatory landscape wherein states were left to supervise the introduction of new medical devices as they saw fit. Id., at 316, 128 S.Ct. at 1003; Medtronic, Inc. v. Lohr, 518 U.S. 470, 475-476, 116 S.Ct. 2240, 2245-46 (1996).

The MDA contains the following express pre-emption provision:

> Except as provided in subsection (b) of this section [which permits the FDA to exempt some state and local requirements from pre-emption], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (2010); Riegel, 552 U.S. at 316, 128 S.Ct. at 1003. The MDA also provides for varying levels of FDA oversight by class. See § 360c(a)(1). Class III medical devices receive the most oversight, including "a rigorous regime of premarket approval" for new devices. Riegel, at 317, 128 S.Ct.

at 1003. The Supreme Court has interpreted state common law tort claims to impose duties which are "requirements" under the MDA's pre-emption provision and has accordingly held that such claims regarding Class III devices are pre-empted by the MDA "to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. Id., at 330, 128 S.Ct. at 1011 (quoting § 360k(a)(1)). Nonetheless, such claims are not pre-empted where they are "premised on a violation of FDA regulations." Id. In such an instance, "the state duties . . . 'parallel,' rather than add to, federal requirements." Id. (quoting Lohr, 518 U.S. at 495, 116 S.Ct. at 2240).

Here, it is undisputed that Alcon's ReSTOR® lens and DisCoVisc® products are Class III medical devices and that Alcon has been granted premarket approval by the FDA for those products. Plaintiffs argue, however, that their negligent manufacturing claim against Alcon is not pre-empted by the MDA because they allege that one or more of Alcon's products deviated from the manufacturing process and was manufactured improperly in violation of federal regulations. Accordingly, Plaintiffs contend, said claim parallels, rather than adds to, federal requirements.

Regarding whether a state tort claim parallels a federal requirement in the context of, as here, a product which is a Class III medical device that has received premarket approval ("PMA") by the FDA, the Court of Appeals for the Fifth Circuit has aptly noted that "products liability claims that purport to impose liability on [a manufacturer] despite [its] compliance with the applicable FDA design and manufacturing specifications, as approved by the FDA during the PMA process, seek to impose different or additional state duties and are expressly preempted." Hughes v. Boston Scientific Corp., — F.3d —, —, 2011 WL

184554, at *5 (5th Cir. 2011) (citing Riegel, at 325, 128 S.Ct. at 999).

Here, Plaintiffs allege that Alcon breached its duty to supply products free from contamination when it sold such products to Dr. Arleo and/or CMC, which posed an unreasonable danger to patients and as a result, caused injury to Mrs. Cafferty. See Compl. ¶¶ 30-32. In opposing Alcon's motion for summary judgment as to this cause of action regarding Alcon's ReSTOR® lens and DisCoVisc® products, Plaintiffs assert that "Alcon most likely violated federal regulations and requirements in connection with the manufacturing" of these devices. Pls.' Mem. of Law in Opp'n to Alcon's Mot. for Summ. J. at 10, Dkt. No. 61. However, this is not a case, as in Purcell v. Advanced Bionics Corp., No. 3:07-cv-1777-M, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008), cited by Plaintiffs, where the court found no MDA pre-emption of a state common law strict liability claim that was predicated solely on an allegation that the product at issue was defective because it was manufactured in violation of FDA's PMA process. See id. at *3. Here, it is undisputed that Alcon's ReSTOR® lens and DisCoVisc® products obtained premarket approval by the FDA. Yet, Plaintiffs fail to direct the court to any evidence in the record that Alcon violated any federal regulations, much less regulations governing the PMA process. See Pls. Resp. to Alcon's Statement of Material Facts, Dkt. No. 61.

Nor is it relevant, as Plaintiffs argue, that this action involves a claim which relies on the res ipsa loquitur doctrine. Other courts have noted that the res ipsa loquitur doctrine, which permits an inference of negligence from circumstantial evidence, seems to be refuted by Riegel, wherein the Supreme Court acknowledged that under the federal law governing the PMA process, there is no demand that a product be risk-free, only that its benefits, if manufactured

according to specifications, outweigh its risks. See Funk v. Stryker Corp., 673 F.Supp.2d 522, 531 (S.D. Tex. 2009) (citing Riegel, at 318, 128 S.Ct. at 1004). See also Clark v. Medtronic, 572 F.Supp.2d 1090, 1094 (D. Minn. 2008). It would follow, then, that one may not infer a manufacturing defect without creating a duty that adds to, rather than parallels, federal requirements in contravention of Supreme Court precedent.

For these reasons, Plaintiffs' negligence claim against Alcon is dismissed only insofar as it relies on a manufacturing defect in Alcon's ReSTOR® lens or DisCoVisc® product, as said claim is preempted by the MDA.

B. Res Ipsa Loquitur

Plaintiffs and each defendant seek summary judgment in their favor on the issue of res ipsa loquitur. Res ipsa loquitur is an evidentiary doctrine[3] that allows a jury to infer negligence from the circumstances of an occurrence. See Kambat v. St. Francis Hosp., 678 N.E.2d 456, 458, 89 N.Y.2d 489, 495 (1997). See also Morejon v. Rais Constr. Co., 851 N.E.2d 1143, 1148-49, 7 N.Y.3d 203, 211 (2006). "Where the actual or specific cause of an accident is unknown, under the

[3] Alcon also files a cross motion as part of its opposition to Plaintiffs' motion for summary judgment, seeking to dismiss Count V of the Complaint, wherein Plaintiffs purport to allege a separate cause of action based upon the doctrine of res ipsa loquitur. See Compl. ¶¶ 33-38. As Alcon correctly points out, res ipsa loquitur is merely an evidentiary rule relating to the sufficiency of a plaintiff's proof on a negligence claim, and as such does not constitute a separate cause of action. See Frew v. Hosp. of Albert Einstein Coll. of Med. Div. of Montefiore Hosp. & Med. Ctr., 428 N.Y.S.2d 300, 301, 76 A.D.2d 826, 826 (N.Y. App. Div. 1980). Because Plaintiffs here have alleged negligence claims against each defendant, the purported cause of action based on the res ipsa loquitur doctrine is redundant, and is dismissed. Nonetheless, Plaintiffs' allegations in support of that purported cause of action shall remain as part of the Complaint because those allegations properly convey notice to defendants of Plaintiffs' theory of liability on their negligence claims in accordance with Rule 8 of the Federal Rules of Civil Procedure.

doctrine of res ipsa loquitur a jury may in certain circumstances infer negligence merely from the happening of an event and the defendant's relation to it." Kambat, at 458, 89 N.Y.2d at 494. A prima facie case of negligence exists, and the plaintiff is entitled to have res ipsa loquitur charged to the jury where (1) the event is of a kind that ordinarily does not occur in the absence of someone's negligence; (2) the event caused by an agency or instrumentality within the exclusive control of the defendant; and (3) the event must not have been due to any voluntary action or contribution on the part of the plaintiff. See id. The New York Court of Appeals further instructs that

> [t]o rely on res ipsa loquitur a plaintiff need not conclusively eliminate the possibility of all other causes of the injury. It is enough that the evidence supporting the three conditions afford a rational basis for concluding that it is more likely than not that the injury was caused by defendant's negligence. Stated otherwise, all that is required is that the likelihood of other possible causes of the injury be so reduced that the greater probability lies at defendant's door.

Id., at 494-95 (internal quotation and citation omitted).

Where, as is alleged here, multiple defendants are in joint and exclusive control of the agency or instrumentality that caused the injury, it is left to those defendants to explain their action and conduct. See Thomas v. New York Univ. Med. Ctr., 725 N.Y.S.2d 35, 36, 283 A.D.2d 316, 317 (N.Y. App. Div. 2001) (citing Schroeder v. City & County Sav. Bank, 57 N.E.2d 57, 293 N.Y. 370 (1944); Kerber v. Sarles, 542 N.Y.S.2d 94, 95, 151 A.D.2d 1031, 1032 (N.Y. App. Div. 1989)).

Regarding the proper analysis of the issue of res ipsa loquitur on a motion for summary judgment, the New York Court of Appeals has instructed that courts

should simply evaluate the circumstantial evidence, and proceed as follows:

> If that evidence presents a question of fact as to the defendant's liability under [this court's] test for res ipsa loquitur, the case should go to trial. If the circumstantial evidence does not reach that level and present a question of fact, the defendant will prevail on the law. Alternatively, as we have said, the plaintiff should win summary judgment [] *in the exceptional case* in which no facts are left for determination.

Morejon, 851 N.E.2d at 1149, 7 N.Y.3d at 212 (emphasis added). Here, as will be discussed, the record contains questions of fact regarding each of the elements under the test for res ipsa loquitur. Accordingly, the motions for summary judgment by Plaintiffs, Alcon, Dr. Arleo and CMC regarding whether there is an inference of negligence based on the doctrine of res ipsa loquitur are denied.

(1) Whether TASS is the kind of injury that ordinarily does not occur in the absence of someone's negligence.

Plaintiffs argue that TASS is not spontaneous and occurs in the majority of cases due to the two sources outlined by Dr. Mamalis, and agreed to by Dr. Armesto, both of which can be avoided with due care.

At his deposition, Dr. Armesto agreed that there may be cases in which some negligence plays a part and results in TASS, but there are also cases where everyone involved does everything they can appropriately and despite their best efforts, TASS can still occur. See Dep. of David M. Armesto, M.D., Feb. 2, 2010 ("Armesto Dep."), 22:20-23:6, at Ex. D to Aff. of James F. Moran, Apr. 26, 2010, Dkt. No. 53 ("Moran Aff."). In his report, Dr. Armesto stated that "TASS is a well-reported complication of cataract surgery that can occur in the best of hands and can vary in presentation[]." Ex. F to Decl. of Oliver N. Blaise, III, Apr. 27, 2010, Dkt. No. 52 ("Blaise Decl."). At his deposition, when asked to explain what

he meant by "in the best of hands," Dr. Armesto stated that "even under the circumstances of perfectly performed surgery, TASS can still present itself and create a devastating complication." Armesto Dep., 8:22-9:2, at Ex. D to Moran Aff.

By affidavit, Dr. Mamalis stated that "TASS is not a complication that occurs only due to negligence. An occurrence of TASS does not necessarily indicate negligence on the part of any party." Mamalis Aff., ¶ 8.

Drs. Armesto and Mamalis both indicate that TASS can occur due to negligence and that it can also occur in the absence of negligence. However, the legal standard is whether TASS is the kind of injury that *ordinarily* does not occur in the absence of someone's negligence. Accordingly, a question of fact exists regarding whether this standard is met here as the evidence creates a question as to how often negligence is a factor in TASS cases.

(2) Whether Mrs. Cafferty's TASS was caused by an agency or instrumentality within the exclusive control of the defendants.

Regarding CMC, Plaintiffs allege that the cleaning and sterilization of opthalmic instruments used during Mrs. Cafferty's surgery was within its exclusive control and that it was the responsibility of CMC to mix and prepare solutions and products for the surgery. CMC admits this assertion except to the extent that disposable opthalmic instruments are used and also notes that Alcon provides some of the preparations, solutions and products. Thus, to the extent CMC admits it was responsible for cleaning and sterilizing some of the instruments used in Mrs. Cafferty's surgery, Plaintiffs have established sufficient control by CMC to at least create a question of fact regarding same.

Regarding Dr. Arleo, Plaintiffs allege, and it is undisputed that, he selected

all of the products and solutions used in Mrs. Cafferty's surgery and placed some of these products and solutions in the anterior segment of Mrs. Cafferty's left eye. This alone is enough to establish sufficient control by Dr. Arleo of the agency or instrumentality which caused Mrs. Cafferty's TASS. Also significant is Dr. Arleo's testimony, while reviewing the video recording of Mrs. Cafferty's surgery, that during the surgery, he removed the DisCoVisc® and noted that he was able to see an "acceptable level of removal" but that if he "looked hard [he] could probably find some, but it's – it's the correct amount of removal." Dep. of Robert Arleo, M.D., Nov. 9, 2009, 136:6-24 ("Arleo Dep."), at Ex. G-2 to Blaise Decl., Dkt. No. 52-13. To be sure, Dr. Mamalis, who viewed the video, testified that he did not find a breach in the standard of care by Dr. Arleo . See Dep. of Nick Mamalis, M.D., Feb. 23, 2010 ("Mamalis Dep."), 86:14-23, at Ex. E to Blaise Decl. Nonetheless, a question exists regarding Dr. Arleo's exclusive control under the res ipsa loquitur standard.

Plaintiffs also argue that there is circumstantial evidence that "Dr. Arleo is ... known to be a fast surgeon, rushing CMC staff to clean and sterilize instruments for reuse later in the day." Pls.' Reply Mem. of Law, at 3, Dkt. No. 71-1. Plaintiffs rely on this alleged evidence to argue that because Dr. Arleo is known to be a fast surgeon, he may not have adequately flushed the DisCoVisc® out of the anterior segment of Mrs. Cafferty's left eye, and CMC staff may have felt rushed during the cleaning and sterilization process, which could have led to inadequate cleaning and sterilization of instruments that were used in an earlier surgery on October 12, 2005 and then reused in Mrs. Cafferty's surgery that same day. See id., at 7. In support of their assertion that Dr. Arleo is known to be a fast surgeon, Plaintiffs cite the entirety of a sealed exhibit, which is over fifty pages in

length. The court's review of that exhibit reveals an electronic message which ostensibly provides the sole basis for Plaintiffs' assertion. However, as Plaintiffs have failed to establish the foundation for same, the evidence is inadmissible.

To be sure, there is evidence in the record that Dr. Arleo may have performed as many as twenty surgeries on the day of Mrs. Cafferty's surgery, at the rate of about four per hour, and that Mrs. Cafferty's surgery took less than four minutes. However, the record is devoid of any evidence regarding what is considered "fast" for the particular type of surgery performed.

Lastly, regarding Alcon, Plaintiffs allege that it manufactured the lens, the solutions contained in the surgical pack and the Aqualase® device that were used in Mrs. Cafferty's surgery. Alcon admits that the records reflect that a ReSTOR® lens, which it manufactured, was implanted during Mrs. Cafferty's surgery, but that the other products have not yet been sufficiently identified. As previously decided herein, Plaintiffs' claim against Alcon is preempted insofar as it is based on claims of negligent manufacturing of Alcon's ReSTOR® lens or DisCoVisc® products.

Alcon argues that many other instruments, medications and solutions were used in Mrs. Cafferty's surgery, yet none of the manufacturers of those products have been named in this lawsuit. Plaintiffs note, however, that the only items accessing the interior segment of Mrs. Cafferty's left eye were (1) alleged nonpreservative lidocaine; (2) surgical instruments used by Dr. Arleo and cleaned/sterilized by CMC (one of which, Aqualase®, is an Alcon product) ; (3) DisCoVisc® (Alcon); (4) ReSTOR® lens (Alcon); and (5) balanced salt solution (BSS®) (Alcon), or inadvertently, distilled water. See Exs. A, G-1 and G-2 to Blaise Decl., Dkt. No. 52. Plaintiffs further note that the manufacturer of the

lidocaine used in Mrs. Cafferty's surgery cannot be identified because CMC failed to record same.

Alcon submits statements from two of its employees – a regulatory compliance manager and a director of corporate quality assurance – as evidence that the ReSTOR® lens used in Mrs. Cafferty's surgery as well as Alcon's other products that were used in her surgery, Aqualase®, DisCoVisc® and BSS®, were not defective at the time they left Alcon's control. See Aff. of Sandra Budden, Apr. 20, 2009, Dkt. No. 27-1; Decl. of Christopher Danford, Apr. 30, 2010, Dkt. No. 57-4. The New York Court of Appeals has noted, however, that res ipsa loquitur may still apply if there is evidence that the instrumentality has not been improperly handled after control was relinquished by the manufacturer. See Corcoran v. Banner Super Mkt., Inc., 227 N.E.2d 304, 306, 19 N.Y.2d 425, 431, 280 N.Y.S.2d 385, 388 (1967). Here, CMC has introduced evidence of its proper handling of Alcon products. See Dep. of Jo A. Marion, Jan. 25, 2010, 56:7-17, 89:3-5, at Ex. E to Aff. of Maria E. Lisi-Murray, Apr. 29, 2010, Dkt. No. 56; Dep. of Eileen Paulson, Nov. 9, 2009, 38:6-40:6, 43:16-45:5, 53:9-54:8, 64:2-18, 80:17-24, at Ex. H to Lisi-Murray Aff., Dkt. No. 56; Dep. of Shawn DiPrinzio, Nov. 24, 2009, 71:20-72:5, at Ex. I to Lisi-Murray Aff., Dkt. No. 56. Accordingly, a question of fact exists regarding whether the agency or instrumentality which caused Mrs. Cafferty's TASS was in the exclusive control of Alcon. Again, said question is limited to Alcon's Aqualase® and BSS® products, as Plaintiffs' claim based on negligent manufacture of the ReSTOR® lens or DisCoVisc® is preempted by the MDA.

(3) Whether any voluntary action or contribution on the part of Mrs. Cafferty contributed to her TASS.

Plaintiffs argue that because access to the anterior segment of the eye can only be made with an incision, any pre-operative access can be ruled out, and that because, as evidenced by the record as well as the findings of Dr. Mamalis (which were agreed to by Dr. Armesto), the incision at the close of surgery was water tight, any post operative access can also be ruled out. Considering Mrs. Cafferty was under anesthesia during the surgery, Plaintiffs argue, there is no evidence of any contribution on her part to the cause of her TASS.

Alcon disputes Plaintiffs' assertion in this regard, arguing that the exact cause of Mrs. Cafferty's TASS has not been determined. CMC and Dr. Arleo argue that because material could have gained access to the anterior segment of Mrs. Cafferty's eye either pre or post surgery, a question remains as to whether she could have contributed to her TASS. There is evidence which would support the argument that TASS can occur due to pre or post operative contamination, and evidence which would support Plaintiffs' contrary assertion. Accordingly, a question remains as to whether Mrs. Cafferty could have contributed to her injury.

For all of the aforementioned reasons, the issue of whether res ipsa loquitur should be charged to a jury cannot be determined on this record. Accordingly, the motions for summary judgment by each of the parties regarding this issue are denied. Consequently the motions for summary judgment on Plaintiffs' remaining claims of negligence against Alcon, CMC[4] and Dr. Arleo are also denied.

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[4] CMC argues that the claim against it sounds in medical malpractice. There is nothing in the complaint or the record to suggest that Plaintiffs' cause of action against CMC is anything other than a negligence claim, and consequently, the court construes it as such.

C. Lack of Informed Consent

Dr. Arleo seeks summary judgment in his favor as to Plaintiffs' medical malpractice claim against him based on lack of informed consent. Plaintiffs oppose.

In order to prevail on a medical malpractice claim based on lack of informed consent, a plaintiff must establish "that (1) the practitioner failed to disclose the risks, benefits and alternatives to the procedure or treatment that a reasonable practitioner would have disclosed and (2) a reasonable person in the plaintiff's position, fully informed, would have elected not to undergo the procedure or treatment." Orphan v. Pilnik, 15 N.Y.3d 907, — N.E.2d —, —, 2010 WL 4720757, at *1 (2010) (citing N.Y. PUB. HEALTH LAW § 2805-d (1),(3) (McKinney 2010). Further, "expert medical testimony is required to prove the insufficiency of the information disclosed to the plaintiff." Id. (citing N.Y. C.P.L.R. § 4401-a (McKinney 2010)). "It is well settled that, in a medical malpractice action, [o]n a motion for summary judgment, a defendant doctor has the burden of establishing the absence of any departure from good and accepted medical practice or that the plaintiff was not injured thereby[, and i]n opposition, the plaintiff must submit a physician's affidavit attesting to the defendant's departure from accepted practice, which departure was a competent producing cause of the injury." Messina v. DeBlasi, — N.Y.S.2d —, No. 104742/2007, 2010 WL 4485828, at *3 (N.Y. Sup Ct. Nov. 5, 2010) (citations and quotation omitted).

Here, it is undisputed that prior to her surgery, Mrs. Cafferty signed a consent form affirming that she understood the associated risks and was consenting to the planned surgery. See Dr. Arleo's Statement of Material Facts ("SOMF") ¶ 11 (citing Ex. N to Moran Aff.); Pls. Response to Dr. Arleo's SOMF

¶ 11. It is also undisputed that the consent form signed by Mrs. Cafferty clearly warns of the risk of inflammation, and that the surgery may make her vision worse. See id. It is further undisputed that Mrs. Cafferty's TASS resulted in "moderate to severe inflammation." Dr. Arleo's SOMF ¶ 12 (quoting Mamalis Dep., 37:3); Pls.' Response to Dr. Arleo's SOMF ¶ 12.

Citing expert testimony, Dr. Arleo alleges that TASS was not widely published and discussed within the opthalmic profession until after a nationwide outbreak in 2006. See Dr. Arleo's SOMF ¶ 13 (citing Mamalis Dep., 15). Plaintiffs dispute this allegation and instead argue that the causes of TASS were "somewhat less understood" prior to the 2006 outbreak. See Pls.' Response to Dr. Arleo's SOMF ¶ 13 (quoting Mamlis Dep., 99). Plaintiffs further argue that in 2005, the knowledge of TASS was not as widespread as it was after 2006. See id. (citing Mamalis Dep., 15). In fact, Dr, Mamalis testified that

> [T]here was a major outbreak of TASS that occurred throughout all of North America in 2006. And as a result of that, we presented multiple talks. We did publications on the issue. We did alerts. We did updates on the issue. And so prior to that time, I think that a lot of the information on TASS was below the radar of physicians unless they were specifically looking into it. So [in] 2005, I don't think the knowledge was as widespread as it was after 2006.

Mamalis Dep., 15:15-25.

The parties also cite additional evidence in the record, which was not included in the Statement of Material Facts. Dr. Arleo notes that by affidavit, Dr. Mamalis expanded on his deposition testimony as follows:

> The standard of care in 2005 did not require specific discussion of TASS with every patient in order to obtain

> informed consent. Even today, [the] standard of care does not require that the patient be informed of the risk by specific reference to TASS by name, or that the physician use other technical medical terminology. The content of the consent forms signed by Mrs. Cafferty prior to her surgery confirm that she was adequately informed of risks associated with the procedure.

Mamalis Aff., ¶ 6, at Ex. H to Moran Aff. Accordingly, Dr. Arleo has met his burden of establishing the absence of any departure from good and accepted medical practice. In order to demonstrate the existence of triable issues of fact, Plaintiffs must "submit a physician's affidavit attesting to [Dr. Arleo's] departure from accepted practice, which departure was a competent producing cause of the injury." Messina, supra. See also Orphan, — N.E.2d at —, 2010 WL 4720757, at *1. Plaintiffs fail to meet this burden.

For their part, Plaintiffs point out that although Mrs. Cafferty initially contacted Dr. Arleo with the intent to undergo Lasik surgery so that she would no longer need to wear glasses, Dr. Arleo convinced her to undergo a lens extraction, stating that she would be a "perfect candidate" and would receive greater benefits from the lens extraction rather than the Lasik. See Arleo Dep., 11:22-13:9; Dep. of Faye Cafferty, Aug. 24, 2009, 16:11-17:4, at Ex. C to Lisi-Murray Aff., Dkt. No. 56. Plaintiffs also correctly note that Dr. Arleo failed to inform Mrs. Cafferty that the procedure could result in the contraction of TASS. In addition, Plaintiffs allege, citing an attorney affidavit for support, that Dr. Arleo did not inform Mrs. Cafferty "that the use of the [ReSTOR®] lens in her circumstance was considered 'off label' and not approved by the FDA." Pls.' Mem. of Law in Opp'n to Arleo's Mot. for Summ. J. at 2, Dkt. No. 62 (citing Aff. of Lisa M. Robinson, Apr. 30, 2010, ¶ 27x ("Robinson Aff.")). It should be noted that the record, for purposes of

a motion for summary judgment, does not include attorney affidavits, as the purpose of an attorney affidavit is to provide background and is not made on personal knowledge. See N.D.N.Y. R. 7.1(a)(3); Fed. R. Civ. P. 56(c)(4). See also Randell v. U.S., 64 F.3d 101, 109 (2d Cir. 1995). To be sure, the cited affidavit is used to usher in admissible evidence, including the physician labeling for Alcon's ReSTOR® lens, which provides, under the heading, "Indications" that the lens "is intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbypoia, who desire near, intermediate and distance vision with increased spectacle dependence." Ex. Q to Robinson Aff. Plaintiffs fail to cite any other evidence, much less evidence in the form of expert testimony, to substantiate their allegation that Dr. Arleo's failure to disclose the intended use of the ReSTOR® lens constitutes an insufficiency of consent within the meaning of C.P.L.R. § 4401-a. Nor have Plaintiffs adduced any evidence that "a fully informed reasonable person would have declined the procedure." Orphan, — N.E.2d at —, 2010 WL 4720757, at *1. In fact, the court's independent review of Mrs. Cafferty's entire deposition transcript reveals no question or answer regarding this issue. See Ex. C to Lisi-Murray Aff., Dkt. No. 56.

Accordingly, because Dr. Arleo has established the absence of any departure from good and accepted medical practice, and Plaintiffs have failed to submit expert evidence of Dr. Arleo's departure from accepted practice, Dr. Arleo's motion for summary judgment on the medical malpractice claim based on lack of informed consent is granted.

VI. Conclusion

In accordance with the foregoing, it is hereby ORDERED that the motion

for partial summary judgment by plaintiffs Faye Cafferty and Doane Cafferty, see Dkt. No. 52, is DENIED, and it is further

ORDERED that the cross motion for partial summary judgment by defendant Alcon Laboratories, Inc., see Dkt. No. 69, is GRANTED in part and DENIED in part, and it is further

ORDERED that the motion for summary judgment by defendant Cayuga Medical Center, see Dkt. No. 56, is DENIED, and it is further

ORDERED that the motion for summary judgment by defendant Alcon Laboratories, Inc., see Dkt. No. 57, is GRANTED in part and DENIED in part; and it is further

ORDERED that the motion for summary judgment by defendants Arleo Eye Institute and Robert Arleo, M.D., see Dkt. No. 53, is GRANTED in part and DENIED in part, and it is further

ORDERED that the motion to dismiss and to stay discovery by defendant Alcon Laboratories, Inc., see Dkt. No. 20, is DENIED as moot.

IT IS SO ORDERED.

DATED: February 8, 2011
Syracuse, New York

Neal P. McCurn
Senior U.S. District Judge